DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 4 2003

SGMP Company Limited
C/O Ms. Janna P. Tucker
Official Correspondent
Tucker & Associates
198 Avenue De La D' emerald
Sparks, Nevada 89434-9550

Re: K023537
Trade/Device Name: Non-Sterile Powder Free Green Latex Patient Examination Gloves with Nopal/Aloe Vera/Vitamin E and Donning Aid Coating, and With Protein Labeling Claim (<50uG/G)
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: September 16, 2003
Received: September 17, 2003

Dear Ms. Tucker:

This letter corrects our substantially equivalent letter of November 20, 2003 regarding the address.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K023537

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APPENDIX N

510(k) SUMMARY FOR:

NON-STERILE POWDER FREE GREEN LATEX PATIENT EXAMINATION GLOVES WITH NOPAL/ALOE VERA/VITAMIN E AND DONNING AID COATING, AND WITH PROTEIN LABELING CLAIM (<50ug/dm2)

Contact person : Cheah Chor Hee

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Device Information:
Trade Name - NON-STERILE POWDER FREE GREEN LATEX PATIENT EXAMINATION GLOVES WITH NOPAL/ALOE VERA/VITAMIN E
Common Name - Exam gloves
Classification Name - Patient examination glove (per 21 CFR 880.6250)
Classification Information - Class I latex patient examination glove 80LYY, powder free and meeting all the requirements of ASTM-D3578-01aE2 Standard Specification for Latex Examination Gloves for Medical Application.

Device Description:
Class I latex patient examination gloves 80LYY, powder free and meeting all the requirements of ASTM-D3578-01aE2 Standard Specification for Latex Examination Gloves for Medical Application.

Intended Use of Device:
A medical glove to be worn on the hand of the health care and similar personnel to prevent contamination between health care personnel and patient.

Technological Characteristics of Device:

1. Dimension

DIMENSION	ASTM D3578-01aE2	SGMP
X-Small Small Medium Large	70 mm +/- 10 mm 80 mm +/- 10mm 95 mm +/- 10mm 111mm +/- 10mm	70 - 75 mm 80 - 85 mm 95 - 97 mm 105 - 111 mm
Length	230 mm minimum for all sizes	242mm
Thickness - Finger Palm	0.08mm min 0.08mm min	0.08 mm min 0.08 mm min

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2. Physical Properties (ASTM-D3578-01aE2 Standard Specification for Latex Exam Gloves) on Lot# 2206

	TENSILE STRENGTH		ULTIMATE ELONGATION	
	ASTM-D3578-01aE2	SGMP	ASTM-D3578-01aE2	SGMP
	Mpa	Mpa	%	%
Before Aging	14.0		700	
X-Small		22.0		770
Small		22.8		790
Medium		24.7		830
Large		23.5		820
After Aging	14.0		500	
X-Small		25.4		860
Small		25.2		810
Medium		25.6		860
Large		24.3		840

3. Water Tight Test

Using the FDA specified 1,000 ml water leak test, 125 pieces of each size of the gloves were tested and our results are as given below:

LOT #	SIZE	SAMPLE SIZE	LEAK STATUS	NUMBER LEAKED
UN-AGED				
2206	X-Small	125	Yes	1
2206	Small	125	No	0
2206	Medium	125	Yes	1
2206	Large	125	Yes	2
AGED				
2206	X-Small	125	No	0
2206	Small	125	Yes	1
2206	Medium	125	Yes	2
2206	Large	125	Yes	1

The above figures are within the FDA/ASTM D3578-01aE2 requirements for latex exam gloves of 2.5% AQL.

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4. Biocompatibility

The bio-compatibility test results are as per Appendix M which shows that the gloves passed the tests in question.

5. Total Residual Powder Content & Presence of Cornstarch

TESTS	FDA INTERNAL REQUIREMENT	SGMP's
Residual Powder Content (ASTM D 6124-06)	2 mg/glove max	Range: 0.5-0.8mg/glove Mean : 0.63 mg/glove
Presence of Cornstarch	Negative	Negative

6. Residual Protein Level

TESTS	FDA ALLOWABLE LEVEL	CLAIMED LEVEL
ASTM D 5712-99	< 50 µg/g	< 50 µg/g

Conclusion:-

The data presented indicate that the Powder Free latex examination glove

1. meets/exceeds ASTM- D3578-01aE2 Standard Specification for Latex Examination Gloves
2. meets FDA pinhole requirements,
3. meets FDA claim criterion of a powder free glove.
4. meets the protein labeling claim level at <50 µg/g.

INDICATIONS FOR USE

APPLICANT: **SGMP COMPANY LIMITED**

510(k) NUMBER: K023537

DEVICE NAME: **NON-STERILE POWDER FREE GREEN LATEX PATIENT EXAMINATION GLOVES WITH NOPAL/ALOE VERA/VITAMIN E AND DONNING AID COATING, AND WITH PROTEIN LABELING CLAIM (< 50uG/G)**

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susana F. Barrero

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023537

Prescription Use____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

 Revised 11-19-03 gt